Message

From: Alwood, Jim [Alwood.Jim@epa.gov]
Sent: 12/21/2021 5:16:57 PM
To: Le, Madison [Le.Madison@epa.gov]; Salazar, Keith [Salazar.Keith@epa.gov]
Subject: RE: Next whistleblower piece

Ex. 5 Deliberative Process (DP)

Jim Alwood
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From: Le, Madison <Le.Madison@epa.gov>
Sent: Tuesday, December 21, 2021 11:56 AM
To: Salazar, Keith <Salazar.Keith@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>
Subject: RE: Next whistleblower piece

Ex. 5 Deliberative Process (DP)

Madison H. Le
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(Contact via email is best)

From: Salazar, Keith <Salazar.Keith@epa.gov>
Sent: Tuesday, December 21, 2021 11:48 AM
To: Le, Madison <Le.Madison@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>
Subject: RE: Next whistleblower piece

Ex. 5 Deliberative Process (DP)

From: Le, Madison <Le.Madison@epa.gov>
Sent: Tuesday, December 21, 2021 11:35 AM

To: Alwood, Jim <Alwood.Jim@epa.gov>; Salazar, Keith <Salazar.Keith@epa.gov>
Subject: RE: Next whistleblower piece

Thanks, Jim and Keith. Below is the language I proposed.

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From: Alwood, Jim <Alwood.Jim@epa.gov>
Sent: Tuesday, December 21, 2021 11:21 AM
To: Le, Madison <Le.Madison@epa.gov>; Salazar, Keith <Salazar.Keith@epa.gov>
Subject: RE: Next whistleblower piece

Ex. 5 Deliberative Process (DP)

From: Le, Madison <Le.Madison@epa.gov>
Sent: Tuesday, December 21, 2021 10:53 AM
To: Alwood, Jim <Alwood.Jim@epa.gov>; Salazar, Keith Salazar.Keith@epa.gov
Subject: FW: Next whistleblower piece

The reporter's follow up question hits on Don's point this morning. Michal hasn't weighed in yet, so I'm not sure if she would like to respond.

In the meantime, we could try to repropose the paragraph we drafted with Don, and add a bit more to address the follow up Q (see red text). Could you verify the sentence highlighted (i.e., if we informed RAD about this solvent) and provide any other edits?

"If we received this PMN today, we would not treat it differently and would come to the same determination. This PMN substance is a polymer and it qualifies for the Polymer exemption. The solvent in question is not the subject of the PMN, nor is its use required to manufacture the PMN substance and does not change how the solvent is generally used in all of its applications. As mentioned in the previous response, there is a robust process within the Existing Chemical Program to conduct risk evaluations for existing chemicals with potential concern. ~~The New Chemicals Program did alert the Existing Chemical Program of this solvent, per the guidance in the memo during the course of the review of the PMN substance.~~ Going forward, the New Chemicals Program could consider reaching out the company, alerting of potential concerns (if known about a solvent) so that company could consider alternatives."

From: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Sent: Tuesday, December 21, 2021 10:15 AM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Le, Madison <Le.Madison@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>
Subject: FW: Next whistleblower piece

Follow-up from Sharon. **Ex. 5 Deliberative Process (DP)**

From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Tuesday, December 21, 2021 10:10 AM
To: Hamilton, Lindsay <Hamilton.Lindsay@epa.gov>
Cc: Daguillard, Robert <Daguillard.Robert@epa.gov>; Carroll, Timothy <Carroll.Timothy@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Subject: Re: Next whistleblower piece

Hi Lindsay-
I just wanted to follow up because, upon reading your response, I fear that I didn't make it clear that I already discuss the memo you attached in the story. In fact I link to it. And I note that the majority of scientists who were discussing the issue of PCBTF in the paint assessment did NOT agree with the interpretation you give of the memo - that it meant that it was subject to the polymer exemption. To be clear, that was the central dispute, the whistleblowers (3 in this case) and several other EPA staff members who were involved in the discussions — and whose emails I've reviewed — did not believe that the memo made it clear that the dangers of PCBTF should not be included in the assessment. Instead, they had a variety of interpretations of the memo, including that 1) the dangers of PCBTF should be included in the assessment, 2) PCBTF should be sent to the existing chemicals for assessment, 3) if NCD did not include the risks in the assessment, other actions should be taken.

One whistleblower said: "There's a final paragraph stating that if there is nothing done, if we're not going to do the review ourselves, at a bare minimum, the risk managers should be communicating what we found to the chemical company so that they know that they have to take some sort of action."

I'm just sending this in case you want to clarify your response at all.
Thanks,
Sharon

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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

On Dec 20, 2021, at 8:26 PM, Hamilton, Lindsay <Hamilton.Lindsay@epa.gov> wrote:

Hi Sharon,

Here is a response for you. Thanks so much.

EPA and the Office of Chemical Safety and Pollution Prevention are committed to the agency's mission to protect human health and the environment.

Regarding the specific PMN in question:

The PMN substance that is the question of this inquiry is a polymer contained in a paint. The PMN substance is a polymer and it qualifies for the polymer exemption.

As background, the 1985 memo, attached, describes how to address a circumstance in which an existing chemical is included as an intentional component of a PMN substance and when that existing chemical poses risk. Under the referenced policy, the solvent would be referred to the Existing Chemical Program and would not be addressed under the new chemical review because the solvent in question is not intentionally part of the PMN substance. The relevant language from the memo that describes this exemption is found on page 9, item #1. The 1985 memo, while written in the context of TSCA as it existed in 1985, contains guidance that remains useful in reviewing new chemicals under the amended law.

When Congress wrote TSCA in 1976 it exempted every chemical in commerce from having to go through the new chemicals assessment process. The 2016 amendments to TSCA direct EPA to do risk evaluations on the existing chemicals that were grandfathered in under the original law and requires EPA to have at least 20 risk evaluations in process at any given time. EPA is meeting those requirements. While one can accurately state that many of the chemicals that were grandfathered into the 1976 law may pose risks and remain unrestricted under TSCA, the PMN substance subject to this inquiry was not handled inappropriately or inconsistently with TSCA.

Regarding scientific integrity:

Restoring scientific integrity has been a top priority across the Agency since the beginning of the Biden-Harris Administration. Significant efforts are underway to understand and address concerns that have been raised. We are continuing to make improvements to the program and are cooperating fully with the ongoing IG investigation.

EPA's new chemicals program has been engaging in targeted, all-hands-on deck efforts to catalogue, prioritize and improve its procedures, recordkeeping and decision-making practices related to review and management of new chemicals under TSCA. The new chemicals program has already implemented several important changes to provide additional opportunities for resolution of differing scientific opinions, and to allow input into the decision-making by EPA subject matter experts outside of the division. This includes, for example, a revised process for review and finalization of human health risk assessments, and the formation of a new advisory body within the program to review and consider both scientific and science policy issues related to new chemical submissions.

The following are examples of additional actions OCSPP has already taken to address scientific integrity concerns across the office:

- Ongoing cooperation with Inspector General's investigation;
- Implementation of several new processes for scientists to elevate their concerns and get a review wherever there's disagreement;
- A change in the performance metric for the New Chemicals Division, such that expediency of reviews is not the only measure of success, see FY 2022-2026strategic plan draft;
- Series of scientific integrity trainings for the entire office to emphasize the importance of these policies;
- Independent contractor review of the TSCA New Chemicals program to capture feedback from employees and management about any potential workplace barriers and opportunities for organizational improvement; and
- Ongoing collaboration with EPA's Office of Research and Development on furthering scientific research relevant to new chemical reviews.

Responses to your specific questions:

QUESTION: IS THIS ACCURATE, THAT MANUFACTURERS "ALMOST ALWAYS" SUBMIT THE INFORMATION ABOUT THEIR PRODUCTS IN PMNS AS CBI? OR IS IT ALWAYS THE CASE? OR JUST SOMETIMES?]

EPA often receives CBI claims associated with various information within PMNs, and the specific claims (i.e., types of information claimed as CBI) will vary case to case.

[QUESTION: WHEN ARE THOSE 20 ASSESSMENTS EXPECTED TO BE FINALIZED?]

The policy changes associated with TSCA risk evaluations that were announced on June 30 will be carried through to all future risk evaluations, including the next 20 and ongoing manufacturer requested risk evaluations. The Agency is reviewing the next 20 chemicals to determine the extent of the effect of policy changes on the scopes of the risk evaluations. Upon completion of this review, EPA intends to provide updates regarding any changes. Generally, these risk evaluations represent a multi-year effort that, under TSCA, can take up to 3.5 years from the designation as a high-priority chemical to complete.

[QUESTION: IS THERE ANY UPDATE ON THIS? ARE THE 8ES AVAILABLE YET IN CHEMVIEW?]

Due to overarching (staff and contractor) resource limitations, the agency was not able to continue the regular publication of 8(e) submissions in ChemView, a heavily manual process, after 1/1/2019. EPA has continued to take in and review 8e submissions; however, a single staff person was dedicated to processing the submissions for posting to ChemView. That staff person retired in December 2018. Other staff within the unit that would historically also do this type of work were fully occupied conducting other work to increase transparency associated with TSCA new chemicals submissions in response to a commitment made by the past EPA Administrator to Senator Carper. See:https://insideepa.com/daily-news/win-dunns-confirmation-epa-vows-revise-key-tsca-programs.

The TSCA program has been and remains incredibly underfunded. The previous Administration never asked Congress for the necessary resources to reflect the agency's new responsibilities under amended TSCA. The Biden-Harris Administration has asked for significantly more resources for this program in the 2022 budget request to ensure we're meeting our obligations under TSCA, most importantly protecting human health and the environment.

In the future, as resources allow, EPA will continue to strive to make TSCA 8(e) reports publicly available in ChemView in the interest of increased transparency. In the meantime, in 2021 EPA reinstated contractor funding to ensure all TSCA 8(e) reports receive initial screening and any serious health and safety risks are flagged for further review. EPA is also currently transforming the 8(e) publication process

to be more automated and to the extent that resources allow, will resume making these submission types publicly available in ChemView again soon.

Thanks,
Lindsay